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CHEMICAL CONTROL BY THE NUMBERS . . . BIG NUMBERS

Charles L. Franklin

2013 was a watershed year for advocates of Toxic Substances Control Act (TSCA) modernization. After years of debate over one-sided, single-party bills, the late Senator Frank Lautenberg (D-NJ), together with Republican Senator David Vitter (R-LA) and a very small, very disciplined group of policymakers, staff, and stakeholders, surprised most TSCA insiders with a compromise bill, the Consumer Safety Improvement Act (CSIA), S. 1009. And while CSIA received a mixed reception, to say the least, the simple fact is that it provided the first meaningful opportunity for Democrats and Republicans in both Houses to discuss some of the very tricky and technical challenges associated with chemical control in 2013—issues like mandatory testing, appropriate safety standards, confidential business information, vulnerable subpopulations, and state preemption. To date, however, one parochial but critical issue has remained unaddressed in the TSCA modernization debate—how to fund it and staff it.

Not that a few policymakers have not tried. During a recent House hearing on TSCA modernization, at least four different congressional members questioned Jim Jones, the U.S. Environmental Protection Agency's (EPA) assistant administrator in charge of chemical and pesticide control policy, about the level of resources required to support an expanded TSCA program. Jones offered consistent, if understated, responses, indicating that absent additional resources, EPA's rate of progress "would be meaningfully constrained."

Translation: Creating and maintaining a first-class chemical control system is expensive—really expensive—in terms of money, time, and human resources. And the costs do not just fall on the private sector. Policymakers can shift the burden for planning, financing, and conducting environmental, health, and safety testing to industry participants and private labs, and they can even outsource large parts of the risk-assessment and characterization process to the private sector, but, ultimately, the job of validating industry risk findings and making tough risk management decisions across multiple substances, products, companies, and sectors must be done by regulators. Such government functions do not come cheap.

Take EPA's pesticide program, a niche sector of the chemical industry regulated under separate statutory authority due to the unique hazard and exposure risks associated with the manufacture and use of such "economic poisons." Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the 1996 Food Quality Protection Act (FQPA) and supplemented by key provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA regulates the import, manufacture, distribution, and use of pesticides and pesticide products using many of the enhanced regulatory tools being recommended for a modernized TSCA program: pre-submission data requirements and pre-market review requiring an affirmative safety determination for each use and a more stringent safety standard, among other tools.

The result is a "best-in-class" pesticide regulatory framework, to be sure, but also a much greater level of federal oversight, meaning larger commitments of budgetary and EPA staff resources on a chemical-per-chemical basis than currently exist for the much larger universe of industrial chemicals regulated under TSCA.

Consider this: In 2012, EPA's Office of Pesticide Programs required approximately 828 staff and roughly $115 million in budgetary resources, including both Science and Technology (S&T) and Environmental Programs & Management (EPM) funds to register 118 new pesticidal active ingredients (across all divisions); update safety findings for 70 older pesticide active ingredients currently in

commerce (out of a total universe of between 800 and 1200 registered active ingredients); and respond to roughly 1450 other registration and labeling-related requests or amendments relating to existing active ingredients, products, and uses.

During the same period, EPA's Office of Chemical Safety and Pollution Prevention had less than half the dedicated staff and budget to act on roughly 1000 new chemical submissions while trying to make headway in reviewing just a fraction of the 84,000 substances currently on the TSCA Inventory. In short, a modernized toxics program will have to manage ten times the number of new substances and complete retrospective safety determinations for between 50 and 100 times the number of substances handled by the better-funded FIFRA program. Moreover, this ramp-up comes at a time when Congress is pushing to reduce, not expand, EPA's budget.

EPA itself has long recognized that funding is a key factor. As early as 2009, former Administrator Lisa Jackson emphasized in her "Essential Principles for [TSCA reform]" document that any new legislation should give EPA a sustained source of funding and that "manufacturers of chemicals should support the costs of Agency implementation, *including the review of information provided by manufacturers.*" Successful federal licensing programs like FIFRA and FFDCA have addressed this challenge by imposing application and user fees on industry participants.

But while chemical manufacturers likely would support reasonable application and review fees to ensure thorough and timely reviews, would they accept fees of up to $500,000 per substance and two-year review periods as established for new pesticide active ingredients? Would such costs, and the massive increase in the workforce required to support these reviews be politically feasible? Instituting a grand FIFRA/FFDCA-style regulatory framework on the massive pipeline of new and existing chemicals regulated under TSCA sounds wonderful in theory. In practice, it creates the risk that the United States will create another "paper tiger"—impressive in print but uneconomical, and hence, unsustainable, in practice.

The point of this analysis is not to discourage TSCA modernization efforts generally, or to undermine the current bipartisan efforts with CSIA in particular. But as stakeholders on both sides work together to find common ground on the arcane legal and technical details of a compromise bill, they need to ensure that the resulting framework is both politically and financially sustainable, so our colleagues will not be writing articles about yet another failed chemical program in 2050.

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